

REMARKS

Claims 1 - 20 are currently pending with Claims 1 - 13 having been examined and with Claims 14 - 20 having been withdrawn from consideration. In the Office Action, the Examiner requested confirmation of Applicants' earlier provisional election of Claims 1- 13 for examination. On the merits, the Examiner issued a provisional statutory double patenting rejection of Claims 1 - 8 and Claims 12 - 13 based upon copending application serial number 10/768,562. Claims 1 - 7 and 9 - 13 were rejected as allegedly being anticipated by U.S. Patent No. 6,221,402 to Itoh et al. ("Itoh"). Finally, Claims 1 and 3 - 13 were rejected as allegedly being obvious over U. S. Patent No. 4,808,411 to Lu et al. ("Lu") in view of U.S. Patent No. 6,331,316 to Ullah et al. ("Ullah").

Each of the foregoing rejections is respectfully traversed and favorable reconsideration is requested in view of the above amendments and following remarks.

I. **Restriction Requirement.**

In the Office Action, the Examiner issued a requirement that Applicant make an election between the Group I claims (Claims 1 - 13), the Group II claims (Claim 14), and the Group III claims (Claims 15 - 20). During a telephone conference with the Examiner, Applicants' provisionally elected Group I, with traverse. Applicant hereby affirm their election of Group I but this election is again made with traverse and is solely for the purpose of advancing prosecution of this case. It is believed that the requirement to restrict the invention is improper. The claims are sufficiently related that their respective classes would be thoroughly cross-referenced, and many of the same classes would be searched regardless of which group of claims was elected.

The Group I claims are directed to a taste making composition containing an antibiotic. The Group II claim is directed to a method for preparing a taste making composition comprising micropellets containing an antibiotic. The Group III claims are also directed to a method for preparing a taste making composition comprising micropellets containing an antibiotic. Hence all of the claims require that a search for taste making compositions for antibiotics be made.

An examination of the Group I claims will require a search of the same prior art as an examination of the Group II and Group III claims. Each would require searching all of the art relating taste making compositions for antibiotics. Furthermore, separate examination of the three claim groups may lead to inconsistent examinations and likely will result in duplication of effort. It is therefore a more efficient use of Patent Office manpower and resources to examine all claims which are closely related at one time rather than conducting separate examinations.

The mere fact that one set of claims is directed to a method and the other set is directed to an apparatus does not mean a patent cannot be issued containing both sets of claims. Patents are routinely issued containing method and apparatus or method and product claims.

Moreover, restriction is not "required" by 35 U.S.C. § 121 as suggested by the Examiner. Congress wisely gave the Commissioner the "discretion" to require restriction. According to 35 U.S.C. § 121 "... the Commissioner may require the application to be restricted...." (emphasis added). Likewise, the MPEP § 803 lists two criteria that must be present for restriction to be proper:

- 1) The invention must be independent or distinct; and
- 2) There must be a serious burden on the Examiner if restriction is not required (emphasis added).

Because the Examiner has not shown any serious burden if examination of all the claims is conducted and the claims cover closely related subject matter, Applicant respectfully requests the Examiner reconsider and withdraw the restriction requirement and examine Claims 1 - 20 on the merits.

II. The Provisional Double Patenting Rejection.

Next in the Office Action, the Examiner provisionally rejected Claims 1 - 8 and 12 - 13 under Section 101 for double patenting based upon the claims of copending application serial number 10/768,562.

It is noted that the '562 application is a continuation-in-part of the present application and was filed several months after the present application. Further, Applicants have not yet received a substantive Office Action from the Patent Office in regard to the '562 application.

Thus, the current case is further along in prosecution and currently appears likely to advance to an allowance prior to the '562 application. Accordingly, Applicants prefer to refrain from amending the claims in the present case, but will, if necessary, amend the claims in the '562 application at a later time in order to avoid any alleged double patenting difficulties arising from the two applications.

III. The Claimed Invention Patentably Distinguishes Over the Cited References.

Turning now to the merits of the invention vis-a-vis the prior art, the Examiner first has rejected Claims 1 - 7 and 9 - 13 as allegedly being anticipated by the Itoh patent. It is respectfully submitted that this rejection is not well taken as the Itoh reference does not disclose or suggest the claimed invention.

Applicants' claims are directed to a taste masking composition which comprises micropellets containing a typically bitter tasting antibiotic. Applicants have found that the unpleasant taste of the antibiotic may be masked by application of two layers of coatings on the micropellet. The micropellet is first coated with an inner coating comprising at least one cellulose polymer and which does not include an enteric coating polymer. In other words, the inner coating layer does not include any enteric polymers which resist dissolution in the acidic environment of the stomach but subsequently dissolve in the neutral or even basic environment of the intestines. Then the micropellet is coated with an outer coating comprising an enteric coating polymer. The resulting micropellets have a particle size of about 100 μm to about 650 μm . Applicants have found that this combination of coatings is effective in masking the bitter taste of antibiotics while still providing fast dissolution and increased bioavailability of the antibiotic.

Itoh also applies two coating layers to an antibiotic core. However, the inner coating layer of Itoh is substantially different from that called for in Applicants' claims. The inner coating of Itoh is formed from a combination of polymers. These include both cellulose polymers which are not enteric coating polymers as well as up to 30 weight percent of enteric coating polymers such as the methacrylate copolymer, EUDRAGIT NE 30 D which are excluded from the inner coating of the claimed invention. Use of the enteric coating polymers

in the inner coating would likely increase the dissolution time and reduce the bioavailability of Itoh's antibiotic composition. Therefore, it is clear that not only does Itoh not anticipate the claimed invention, it in fact teaches away from the claimed invention.

Accordingly, it is submitted that the anticipation rejections based upon Itoh are overcome and should be withdrawn.

Additionally, the Examiner contends that Claims 1 and 3 - 13 are obvious over Lu in view of Ullah. This rejection is not well taken. Neither Lu nor Ullah disclose or suggest the claimed invention, either separately or in combination with one another. At a minimum, this is because neither Lu nor Ullah discloses or suggests a micropellet having both an inner coating which is non-enteric and an outer coating which is enteric.

Lu discloses only a single coating step. While Lu may disclose certain non-enteric cellulose coatings (Col. 4, line 57 - Col. 5, line 2) as well as enteric coatings (Col. 5, lines 3 - 18), these materials are disclosed as alternatives to one another. Lu in no way suggests the use of multiple layers of coatings. In this regard, the examples of Lu are particularly notable. While Lu includes some 14 examples, only examples 5 and 6 disclose the any type of coating process. In both of these examples, only a single coating formulation is applied which is substantially hydroxypropylmethyl cellulose phthalate in solvent mixture.

Ullah also is directed to a composition which employs only a single coating layer which is an enteric coating layer. In fact, Ullah specifically teaches that a goal of the reference is to eliminate any subcoatings beneath the enteric layer (Col 4, lines 26 - 29). Thus, Ullah teaches away from the claimed invention.

The Examiner has failed to show any teaching in the references or other teaching in the art that would motivate a person of ordinary skill to combine the references in the proposed manner. Thus, although Applicants do not believe the combination achieves what they are claiming, even if it did, there is nothing to motivate a person of ordinary skill to make the combination in the first place.

Since neither Lu nor Ullah individually discloses a multi-layer coating for a pharmaceutical micropellet and there is no teaching, in any event, to combine the references to achieve a multi-layer coating as claimed, it is clear that the purported combination of the two

Application No. 10/688,551
December 19, 2005

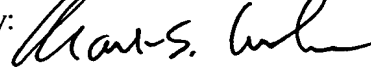
references likewise cannot disclose or suggest the claimed invention. Hence, it is submitted that the obviousness rejections based upon Lu an Ullah are improper and should be withdrawn.

In light of the foregoing, Applicants urge the Examiner to reconsider the application, to withdraw the rejections, and to issue a notice of allowance at the earliest possible convenience.

In the event this response is not timely filed, Applicants hereby petition for the appropriate extension of time and request that the fee for the extension along with any other fees which may be due with respect to this paper be charged to our **Deposit Account No. 12-2355**.

Respectfully submitted,
LUEDEKA, NEELY & GRAHAM, P.C.

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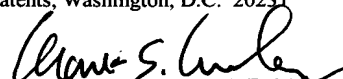
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